STARK & STARK, P.C.
993 Lenox Drive, Building Two
Lawrenceville, New Jersey 08648
Phone: (609) 896-9060; Fax: (609) 896-0629
Martin P. Schrama (PA 324828)
Stefanie Colella-Walsh (PA 205709)
Email: mps@stark-stark.com
scw@stark-stark.com

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

Janet L. Landon and John A. Latschar, individually, and as Administrators of the Estate of Aaron Landon Latschar, Deceased; Plaintiffs, v. Soluciones Cosmeticas, SA de CV; RediBag USA, LLC; Wal-Mart Stores East, LP; WalMart, Inc.; and ABC Corporations 1-20; Defendants.	**COMPLAINT AND JURY DEMAND** CIVIL ACTION NO. _____

PARTIES

1. Janet L. Landon, is an adult individual residing in the town of Gettysburg, Adams County, Pennsylvania.
2. John A. Latschar, is an adult individual residing in the town of Gettysburg, Adams County, Pennsylvania.
3. Janet L. Landon and John A. Latschar (collectively, "Plaintiffs") are the mother and father of Aaron Landon Latschar, deceased ("Decedent").

4. Plaintiffs were appointed co-administrators of the estate of Decedent, on August 21, 2020, by the Register of Wills of Adams County, Pennsylvania.
5. Plaintiffs are legally entitled to recover damages for the death of Decedent, individually, and on behalf of Decedent's estate.
6. Plaintiffs bring this action pursuant to 42 *Pa. Cons. Stat. Ann.* § 8301 and *Pa. R.C.P.* 2202(a) as the personal representatives of Decedent, on their own behalf, and on behalf of all those entitled by law to recover damages for the wrongful death of Decedent.
7. Plaintiffs bring this action on behalf of Decedent's estate pursuant to 20 *Pa. Cons. Stat. Ann.* § 3373 and 42 *Pa. Cons. Stat. Ann.* § 8302 for damages suffered by the estate as a result of Decedent's death as well as for the pain, suffering, and inconvenience which Decedent underwent prior to his death.
8. At no time during his life did Decedent bring an action to recover damages for his personal injuries, and no other action has been commenced to recover damages for his death.
9. Defendant, Soluciones Cosmeticas, SA de CV ("Soluciones"), is a foreign entity organized and existing under the laws of Mexico and having its principal place of business at Avenida Ano De Juarez 110, Otro Granjas San Antonio Iztapalapa, CDMX, Mexico.
10. Soluciones is a consumer health products company that is registered with the United States Food and Drug Administration ("FDA") as a human drug manufacturer.
11. Soluciones is involved in the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of consumer health products, including Bersih Hand Sanitizer ("BHS").
12. Soluciones has derived substantial revenue related to BHS throughout the United States. At all times material herein, Soluciones did business in Pennsylvania.

13. Defendant, RediBag USA, LLC ("RediBag"), is, upon information and belief, a New York limited liability company with its principal place of business and the residence of its members in New York.

14. RediBag is involved in the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of consumer health products, including BHS.

15. RediBag has derived substantial revenue related to BHS throughout the United States. At all times material herein, RediBag did business in Pennsylvania.

16. Defendant, Wal-Mart Stores East, LP, is, upon information and belief, a Delaware limited partnership with its principal place of business in Arkansas, and the residence of its partners outside of New Jersey.

17. Defendant, WalMart, Inc. (collectively, along with Wal-Mart Stores East, LP, "WalMart"), is, upon information and belief, a Delaware Corporation with its principal place of business in Arkansas.

18. WalMart is involved in the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of consumer health products, including BHS.

19. WalMart has derived substantial revenue related to BHS throughout the United States. At all times material herein, WalMart did business in Pennsylvania.

20. Defendants, ABC Corporations 1-20, are unknown entities in the chain of supply and sale of BHS, including, but not limited to developers, manufacturers, packagers, marketers, testers, inspectors, shippers, suppliers, distributors, wholesalers, resellers and/or retailers,

as well as the subsidiary and parent companies of those entities, that did business in Pennsylvania (collectively, along with Soluciones, RediBag, and WalMart, "Defendants").

21. At all times material herein, Defendants were acting directly and/or through their agents, servants and employees, who were acting within the scope and course of their employment, for, and in furtherance of, the business of Defendants.

JURISDICTION AND VENUE

22. Federal subject matter jurisdiction exists under 28 *U.S.C.* § 1332(a), as there is complete diversity of citizenship between Plaintiffs and Defendants, and the amount in controversy exceeds $75,000.

23. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, Defendants are subject to personal jurisdiction in this federal judicial district, as a substantial part of the events giving rise to Plaintiffs' causes of action occurred in this federal judicial district and venue is proper under 28 *U.S.C.* §1391(a).

FACTS COMMON TO ALL COUNTS

24. The COVID-19 global pandemic created an unprecedented demand for hand sanitizers. This spawned a proliferation of companies seeking to fulfill that demand, and a corresponding surge in production.

25. Unfortunately, it soon became clear that certain amoral and purely economically motivated actors were preying upon the emergency engendered by the pandemic and placing substandard, defective and/or adulterated products into the stream of commerce.

26. BHS was just such a product, as it contained undisclosed amounts of methanol. Methanol, also known as methyl alcohol, is a clear, colorless industrial solvent used for such applications as antifreeze, windshield wiper fluid, paint remover, automobile and boat fuel.

27. Methanol has a particularly sweet aroma and taste, but it is a potent and deadly poison. Once a small amount of methanol enters the human body, the methanol is metabolized into toxins such as formaldehyde. This is a slow and painful process preceding severe visual and neurologic damage and, eventually, death.

28. Methanol obviously is not, and has never been, an acceptable ingredient in hand sanitizers, or any over-the-counter products regulated by the FDA or its state counterparts. In fact, aside from being extremely deadly, methanol is not even an effective ingredient for eliminating microbes and germs.

29. However, methanol is much cheaper to produce than ethyl alcohol and there are numerous accounts throughout history of unscrupulous manufacturers adding methanol (or "wood alcohol") to homemade alcoholic beverages. This led to well-documented and tragic methanol poisonings in the United States during prohibition, and more recently throughout the developing world, where strict production guidelines were not enforced.

30. Since it is commonly known that a very small amount of methanol is lethal to humans and animals, throughout the 1980s and 1990s numerous industry groups and governmental entities eventually required the placement of noxious safety related additives in methanol containing products, such as antifreeze and windshield washer fluid. *See* Fanick, E. Robert, *Safety Related Additives for Methanol Fuel*, SAE Transactions, SAE International (1984); Mullins ME, Zane Horowitz B, *Was it necessary to add Bitrex (denatonium benzoate) to automotive products*?, Veterinary and Human Toxicology (2004). In addition, products containing methanol have been required to be placed in specialized safety containers, bearing prominent warnings and directions.

31. None of these longstanding, inexpensive and readily available precautions were taken with BHS. Moreover, Defendants at all times material herein knew full well that BHS contained the poison methanol, but never properly disclosed or warned anyone of that fact. To the contrary, Defendants explicitly denied the fact that BHS contained deadly levels of methanol.

32. Obviously, no one who was properly made aware that BHS was laced with poison would have purchased or used BHS for any purpose. Moreover, Defendants would not have been permitted to put BHS into the stream of commerce, as BHS was unsafe for any reasonable, non-industrial use.

33. Defendants were also aware that hand sanitizers had been widely used and ingested as an alcohol substitute for decades. Ingestion of BHS was a well-known and reasonably anticipated use of the product, as reporting on this issue has been ubiquitous across all medical, entertainment and media platforms.

34. By way of just a few of many examples of this trend in popular culture, a regular character portrayed to be an alcoholic was shown drinking hand sanitizer on a September 2006, episode of the network sitcom "The Office." Similarly, during a segment of "Jimmy Kimmel Live!," first broadcast in April 2012, host Jimmy Kimmel and actor John Cusack discussed this trend as they drank hand sanitizer on air. *See*, *also*:

- https://www.npr.org/sections/health-shots/2012/04/25/151372857/teenagers-latest-bad-idea-drinking-hand-sanitizer;
- https://www.cnn.com/videos/us/2012/04/26/prime-news-bts-teens-hand-sanitizer.hln;
- https://www.cdc.gov/handwashing/show-me-the-science-hand-sanitizer.html#twentysix (*citing* "The rising incidence of intentional ingestion of ethanol-containing hand sanitizers," Crit Care Med. 2012);

- as well as numerous YouTube videos across the internet regarding the widespread "hand sanitizer challenge," where individuals are depicted drinking hand sanitizer.

35. On or around June 26, 2020, Decedent purchased poisonous BHS from WalMart Store #1537, located at 1270 York Rd, Gettysburg, Pennsylvania, near Decedent's home.

36. On or around June 27, 2020, Decedent ingested Defendants' poisonous BHS and thereafter died a horrible and agonizing death.

37. Defendants, as manufacturers, distributors, sellers, and/or advertisers of BHS are held to the level of knowledge of experts in their fields. Consumers, including Decedent, justifiably relied upon the skill, superior knowledge, and judgment of Defendants. Here, Decedent could not have discovered, through the exercise of reasonable care, the deadly ingredients purposefully placed in BHS.

38. The June 29, 2020, autopsy report concluded that Decedent, otherwise healthy, died of "methanol toxicity," and specifically referenced the bottle of BHS found at the scene.

39. That bottle, labeled Bersih Hand Sanitizer Gel 500ml, contains no indication that the BHS was laced with a potent and deadly poison, but, in fact, merely listed the active ingredients as: "Ethyl Alcohol 70%;" and inactive ingredients as: "Water, Propylene Glycol, Carbomer, Sodium Hydroxide." This was clearly and knowingly untrue.

40. Those listed ingredients are largely harmless, as one would expect the ingredients to be in a consumer health product that has a known history of human ingestion. In fact, ethyl alcohol has been consumed for thousands of years and is the principle ingredient in alcoholic beverages. Had BHS actually contained the listed ingredients, it would not have killed Decedent.

41. Particularly tragic is the fact that there are widely known and effective antidotes to acute methanol poisoning, such as fomepizole or ethanol. However, Decedent had no way of

knowing that BHS contained an undisclosed poison and could not have known that a common antidote would have saved his life.

See https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750029.html

42. Defendants, at all times material herein, were aware that BHS contained a potent and deadly poison. Defendants, at all times material herein, were aware that similarly poisonous products had flooded the market, had been, and would continue to be, ingested by consumers, causing widespread reports of serious injuries and deaths.

43. Shortly after the ramp-up in hand sanitizer production in the nascence of the pandemic, the FDA soon began receiving adverse event reports of poisonous hand sanitizers. Ongoing investigation and testing eventually culminated in a June 19, 2020, alert:

> FDA urges consumers not use certain hand sanitizer products
>
> The following chart outlines the information on hand sanitizer labels for consumers to use to identify a product that:
>
> - Has been tested by FDA and found to contain methanol or 1-propanol.
> - Is labeled to contain methanol.
> - Has been tested and is found to have microbial contamination.
> - Is being recalled by the manufacturer or distributor.
> - Is subpotent, meaning it has less than the required amount of ethyl alcohol, isopropyl alcohol or benzalkonium chloride.
> - Is purportedly made at the same facility as products that have been tested by FDA and found to contain methanol or 1-propanol.
> - Is packaged in a container that resembles a food/beverage container that presents increased risk of accidental ingestion.
>
> FDA advises consumers not to use hand sanitizers produced by the manufacturers identified in the table below. Consumers can easily identify which hand sanitizer products to avoid by using the following information:
>
> - The names of the specific manufacturers.
> - NDC number, which may also be located on the product label.
> - The name of the distributors that sell, or sold, or had planned to sell specific hand sanitizers products produced by these manufacturers.

> Distributors may use more than one manufacturer to produce their hand sanitizer products, which are then marketed under the exact same brand or product name. Distributors often do not identify the manufacturer on the product label and are not required to do so under federal law. Consumers should be aware that FDA's recommendation against using a distributor's specific hand sanitizer product(s) manufactured by a particular manufacturer, as listed below, does not extend to:
>
> - A distributor's products bearing the same brand name as listed below, but made by a different manufacturer.
> - Other products distributed by the same distributor.
>
> If a product on the list below does not identify the manufacturer on the label, consumers can contact the distributor whose name appears on the label to find out who manufactured the product. If the distributor refuses to clarify this information when contacted by a consumer, FDA advises consumers not to use that product.

See https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use#products

44. Yet, when the FDA was finally able to start tracking down and addressing the wrongdoers taking advantage of the pandemic in this manner, not only did Defendants fail to take any action to remedy the grave situation they had caused, but Defendants continued in their bald-faced misrepresentations. For example, on June 20, 2020, Defendants issued the following correspondence:

> June 20, 2020
>
> RE: FDA ADVISORY ON ESKBIOCHEM SA de CV SANITIZER PRODUCTS
> LINK: https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-consumers-not-usehand-sanitizer-products-manufactured-eskbiochem
>
> Dear Valued Customers,
>
> Please be advised that the Bersih brand hand sanitizer is **NOT** produced by Eskbiochem S.A. de CV in Mexico. Rest assured that RediBag USA and our sanitizer partner, Soluciones Cosmeticas S.A de C.V. has done the due diligence necessary to ensure the safety of this product and full compliance with FDA requirements. Bersih sanitizer is mixed and bottled by an FDA Establishment (1005284) that has produced quality cosmetics servicing the United States for over 30 years.

> The Bersih sanitizer FDA NDC number is 75165-001-01. You will find this number is **NOT** included on the FDA advisory listing. We hereby confirm that the ethanol used in our product is produced right here in the USA so we can assure our full confidence on its safety, purity and methanol-free formulation. Bersih hand sanitizer is 100% safe to use and every truckload crossing the U.S. border has been reviewed and released by the FDA for sale within the U.S. We will make every effort to continue to provide this COVID-19 essential product to our valued customers and their consumers. If you have any further questions or concerns with our product, please feel free to call us for more information 800.746.0600.
>
> Sincerely,
> Jeff Rabiea
> CEO
> RediBag USA

See https://www.redibagusa.com/wp-content/uploads/2020/04/RediBag-Bersih-Sanitizer-Letter-6.20.20.pdf (emphasis retained)

45. Contrary to Defendants' continued actions, inactions and misrepresentations regarding BHS, FDA testing finally uncovered what Defendants knew, or should have known, all along, BHS contained lethal levels of a potent and deadly poison. Accordingly, despite Defendants' continued misrepresentations, BHS was ultimately added to the FDA's list of similar dangerous products on July 2, 2021:

Manufacturer	Product(s)	NDC(s)	Distributor	Product Status	Date added to table
Soluciones Cosmeticas SA de CV (Mexico)	Bersih Hand Sanitizer Gel Fragrance Free	75165-000-01 75165-001-01 75165-003-02 75165-004-01 75165-005-01 75165-006-01 75165-250-01	Private D Capital Group Corp., Human Choice LLC and RediBag USA Astrum LLC	FDA tested product; contains methanol; FDA recommended the company recall on 7/1/2020; added manufacturer to import alert to help stop their products from entering the U.S. on 7/10/2020; product voluntarily recalled on 7/14/2020 and updated the recall on 8/9/2020; FDA issued a warning letter on 8/4/2020	07/02/2020

See https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use

46. On August 4, 2020, the FDA issued a formal Warning Letter to Defendants, detailing prior discussions and setting forth findings and allegations. Plaintiffs adopt by reference all of the findings and allegations in the FDA's Warning Letter:

Warning Letter 320-20-42

August 4, 2020

Dear Mr. Ali:

Your firm recently registered as a human drug manufacturer. The U.S. Food and Drug Administration (FDA) conducted testing of drug products manufactured at your facility: consumer antiseptic hand rubs (also referred to as consumer hand sanitizers) labeled as BERSIH Antiseptic Alcohol 70% Topical Solution Hand Sanitizer and BERSIH HAND SANITIZER GEL Fragrance Free (referred to collectively as "Bersih HAND SANITIZER drug products"). These drug products were manufactured at your facility, Soluciones Cosmeticas SA de CV, FEI 3011274338, at Avenida Ano De Juarez 110, Otro Granjas San Antonio, Iztapalapa, Ciudad De Mexico MX and, following an attempted import into the United States, were detained and refused admission at the border.

The results of FDA laboratory testing demonstrated that batches of your Bersih HAND SANITIZER drug products are adulterated within the meaning of section 501(d)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(d)(2), in that a substance was substituted wholly or in part therefor. In addition, these products are adulterated within the meaning of section 501(a)(2)(B), 21 U.S.C. 351(a)(2)(B), in that the substitution demonstrates that the quality assurance within your facility is not functioning in accordance with Current Good Manufacturing Practice (CGMP) requirements.

In addition these drug products are unapproved new drugs introduced or delivered for introduction into interstate commerce in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a), and are misbranded under sections 502(j), (a) and (e) of the FD&C Act, 21 U.S.C. 352(j), (a) and (e). Introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(d) and (a) of the FD&C Act, 21 U.S.C. 331(d) and (a). These violations are described in more detail below.

Adulteration Violations

Your drug product, BERSIH Antiseptic Alcohol 70% Topical Solution Hand Sanitizer, is labeled to contain 70% volume/volume (v/v) of the active ingredient alcohol (ethanol). However, FDA laboratory testing of batches of this product detained at the border found that your Antiseptic Alcohol 70% Topical Solution Hand Sanitizer contained an average of 44% ethanol and 30% of methanol v/v. Additionally, BERSIH HAND SANITIZER GEL is labeled to contain 70% v/v of the active ingredient alcohol (ethanol). However, FDA laboratory testing of batches of this product detained at the border found that BHS contained 67% ethanol and 1.6% methanol v/v. Therefore, these hand sanitizer drug products are adulterated under section 501(d)(2) of the FD&C Act in that the active ingredient of ethanol

was substituted wholly or in part with methanol, a dangerous chemical when in contact with human skin or ingested.

Methanol is not an acceptable ingredient for hand sanitizers and should not be used due to its toxic effects. Skin exposure to methanol can cause dermatitis, as well as transdermal absorption with systemic toxicity. Substantial methanol exposure can result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system, or death. Although all persons using these products on their hands are at risk, young children who accidentally ingest these products and adolescents and adults who drink these products as an alcohol (ethanol) substitute are most at risk for methanol poisoning.

On July 1, 2020, FDA held a teleconference with you and your registered U.S. agent, Logicargo US Customs & Bonded Carrier Solutions LLC. We recommended you consider removing all of your firm's hand sanitizer drug products currently in distribution to the U.S. market. As you had not taken action upon our request, on July 2, 2020 FDA notified the public of methanol contamination of your hand sanitizer at the following website: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use.

On July 10, 2020, FDA held a subsequent teleconference with you and your outside counsel to discuss the serious health implications regarding methanol contamination. Subsequently you agreed to recall all of your hand sanitizer drug products, and verified that all your BERSIH Antiseptic Alcohol 70% Topical Solution Hand Sanitizer was refused admission to the United States On July 14, 2020, you issued a voluntary nationwide recall of BERSIH HAND SANITIZER GEL due to potential presence of undeclared methanol (Wood Alcohol), as noted on the following FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/soluciones-cosmeticas-issues-voluntary-nationwide-recall-bersih-hand-sanitizer-gel-due-potential

In response to this letter provide the following:

• A detailed investigation into how hand sanitizer drug products manufactured at your facility, and labeled as containing ethanol, were substituted in part or in whole with methanol.
• A list of all raw materials used to manufacture all of your hand sanitizer drug products, including the suppliers' names, addresses, and contact information.
• A list of all batches of any hand sanitizer drug products shipped to the United States by your firm, and a full reconciliation of all material you distributed.
• Copies of the complete batch records for all batches distributed to the U.S.
• During discussion with FDA, you indicated that one shipment FDA tested and found to have methanol contamination was in fact intended for research purposes only. However, the labeling was indicative of drugs for consumer use (e.g., the labeling included a Drug Facts label) and the shipment was declared as for human

use. Accordingly, when you provide a full list of batches distributed, include any you contend were manufactured for research purposes only.

The substitution and methanol contamination in hand sanitizer drug products manufactured in your facility is evidence that the quality assurance within your facility is not functioning in accordance with CGMP requirements under section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).[1]

Unapproved New Drug and Misbranding Violations

BERSIH Antiseptic Alcohol 70% Topical Solution Hand Sanitizer and BERSIH HAND SANITIZER GEL are "drugs" as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because they are intended for the diagnosis, cure, mitigation, treatment, or prevention of disease and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because they are intended to affect the structure or any function of the body. Specifically, these products are intended as topical antiseptics.

Examples of claims observed on the BERSIH Antiseptic Alcohol 70% Topical Solution Hand Sanitizer product label, that provide evidence of the intended use (as defined in 21 CFR 201.128) of BHS include, but may not be limited to, the following:

> "Hand Sanitizer . . . Drug Facts . . . Uses[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease."

Examples of claims observed on the BERSIH HAND SANITIZER GEL product label, that provide evidence of the intended use (as defined in 21 CFR 201.128) of BHS include, but may not be limited to, the following:

> "HAND SANITIZER . . . SUPPORTS KILLING 99.9% OF GERMS . . . Drug Facts . . . Use to help reduce bacteria on the skin."

These hand sanitizer products are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in their labeling. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a). No FDA-approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for either of these hand sanitizer products, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that your BERSIH Antiseptic Alcohol 70% Topical Solution Hand Sanitizer and BERSIH HAND SANITIZER GEL drug products are GRASE for use under the conditions suggested, recommended, or prescribed in their labeling.

Accordingly, these products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d).

We note that over-the-counter (OTC) topical antiseptic products have been the subject of rulemaking under the Agency's OTC Drug Review. In particular, such products were addressed in a tentative final monograph (TFM) entitled "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM), as further amended by the "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016) and the "Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; and Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 80 FR 25166 (May 1, 2015). Over the course of these rulemakings, benzalkonium chloride, ethyl alcohol, and isopropyl alcohol were classified as Category III, meaning that additional safety and effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as a consumer or health care personnel antiseptic rub.

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), enacted on March 27, 2020, added section 505G to the FD&C Act, which addresses nonprescription drugs marketed without an approved application. Under 505G(a)(3) of the FD&C Act, drugs that were classified as Category III in a TFM that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 – and that were not classified in such a TFM as Category II for safety or effectiveness -- are not required to have an approved application under section 505 in order to be marketed, as long as they are in conformity with the relevant conditions of use outlined in the applicable TFM, including the active ingredient, and comply with all other applicable requirements for nonprescription drugs.

However, your Bersih HAND SANITIZER drug products do not conform to the 1994 TFM, as further amended by the 2016 Consumer Antiseptic Rub proposed rule and the 2015 Health Care Antiseptic proposed rule, nor any other TFM or final rule, and do not meet the conditions under section 505G(a)(3) of the FD&C Act, as added by the CARES Act, for marketing without an approved application under section 505.[2]

According to BHS label, BERSIH Antiseptic Alcohol 70% Topical Solution Hand Sanitizer purportedly contains the active ingredient ethyl alcohol (ethanol) 70% v/v. However, as previously discussed, FDA laboratory analyses revealed that a sample of BERSIH Antiseptic Alcohol 70% Topical Solution Hand Sanitizer contains a concentration of ethanol that is far less than the 70% declared on the

label and far less than the amount of ethanol described in the 1994 TFM.[3] Such a product does not conform with the TFM, nor is it consistent with the formulations described in FDA's temporary policies for hand sanitizers during the COVID-19 public health emergency.

FDA laboratory analyses also revealed that samples of your Bersih HAND SANITIZER drug products contain significant concentrations of the undeclared ingredient methyl alcohol (methanol). Use of methanol as an active ingredient is not in conformance with the TFM, nor is it included in the formulations described in FDA's Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry. Furthermore, methanol is not acceptable as an inactive ingredient in hand sanitizers. As previously discussed, methanol has significant and sometimes fatal toxic effects and, therefore, does not meet the requirements under 21 CFR 330.1(e) that an OTC monograph drug contain only safe and suitable inactive ingredients.[4]

Additionally, these methanol-containing drug products, BERSIH Antiseptic Alcohol 70% Topical Solution Hand Sanitizer and BERSIH HAND SANITIZER GEL, are misbranded under sections 502(j), (a), and (e) of the FD&C Act, 21 U.S.C. 352(j), (a), and (e). They are misbranded under section 502(j) of the FD&C Act, 21 U.S.C. 352(j), because they are dangerous to health when used according to their labeling as hand sanitizers. As previously stated, skin exposure to methanol could lead to systemic absorption. Substantial methanol exposure can potentially result in, among other things, blindness, permanent nervous system damage, and even death. These hand sanitizers are misbranded under section 502(a) of the FD&C Act, 21 U.S.C 352(a), because their labeling is false and misleading. As noted above, BERSIH Antiseptic Alcohol 70% Topical Solution Hand Sanitizer is labeled to contain ethyl alcohol 70% v/v. However, FDA laboratory analysis revealed that a sample of this product contains less ethyl alcohol than indicated on the labeling and instead contains significant concentrations of methyl alcohol (methanol), an ingredient that is not declared on BHS labels.

Section 201(n) of the FD&C Act, 21 U.S.C. 321(n), provides that "in determining whether the labeling or advertising is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result. . .." As such, the label representation that BERSIH Antiseptic Alcohol 70% Topical Solution Hand Sanitizer contains 70% ethyl alcohol when it does not, as well as the failure of both BHS labels to disclose the presence of the methyl alcohol in BHSs, causes these products to be misbranded under section 502(a) of the FD&C Act, 21 U.S.C. 352(a). Lastly, the failure of these products to list methyl alcohol (methanol) as an ingredient on their labels causes them to be misbranded under section 502(e)(1)(A) of the FD&C Act, 21 U.S.C. 352(e)(1)(A).

The introduction or delivery for introduction of a misbranded drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations associated with your drug products. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence or the occurrence of other violations.

Note that FDA placed all drugs and drug products manufactured by your firm on Import Alert 66-78 on July 10, 2020.

All drugs and drug products manufactured by your firm will remain listed on this import alert until the concerns with your drugs are adequately addressed and verified by FDA.

If you decide you want to manufacture drugs for the United States in the future, request a Regulatory Meeting to discuss corrective actions required prior to an FDA inspection. Until FDA is able to inspect your facility, we may withhold approval of any new applications or supplements listing your firm as a drug manufacturer.

In addition, shipments of articles manufactured at Soluciones Cosmeticas SA de CV, Avenida Ano De Juarez 110, Otro Granjas San Antonio, Iztapalapa, Ciudad De Mexico MX into the United States are subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3) in that they appear adulterated under section 501 of the FD&C Act, 21 U.S.C. 351.

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov

Identify your response with FEI 3011274338 and ATTN: Daniel W. Brisker.

Sincerely,
/S/
Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

CC:
Registered US Agent
Alejandro R Zamudo
Logicargo US Customs & Bonded Carrier Solutions LLC
410 Nafta Blvd Laredo TX 78045

CC:
Outside Counsel
Jessica P. O'Connell
Covington & Burling LLP
One CityCenter, 850 Tenth Street, NW
Washington, DC 20001-4956

---

[1] Due to an increased demand for alcohol-based hand sanitizers during the COVID-19 pandemic, FDA published the Guidance for Industry: *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)* on March 19, 2020, and subsequently updated the guidance on March 27, April 15 and June 1 of 2020. This guidance communicates the Agency's temporary policy that we do not intend to take action against firms for CGMP violations under section 501(a)(2)(B) of the FD&C Act if such firms prepare alcohol-based hand sanitizers for consumer use (or for use as health care personnel hand rubs) during the public health emergency, provided certain circumstances described in the guidance are present. These circumstances include preparation of hand sanitizer products using only the ingredients and formulas set forth in the guidance. In addition to the violative sample results detailed above that demonstrate the presence of methanol in your hand sanitizer products, review of the formulations on your drug product labeling further indicate that such products are not prepared consistent with FDA's temporary policy set forth in the guidance. Therefore, these products do not fall within the Agency's temporary policy not to take action against firms manufacturing hand sanitizer products for violations of section 501(a)(2)(B) of the FD&C Act.

[2] Furthermore, BERSIH Antiseptic Alcohol 70% Topical Solution Hand Sanitizer and BERSIH HAND SANITIZER GEL do not fall under any temporary policy for hand sanitizers that FDA has implemented in response to the COVID-19 public health emergency. See https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-guidance-production-alcohol-based-hand-sanitizer-help-boost

[3] The 1994 TFM, which does not distinguish between antiseptic hand washes and rubs, proposed for antiseptic handwashes and healthcare personnel handwashes an alcohol concentration of 60 to 95% by volume in an aqueous solution. 59 FR at 31442. Later amendments to the 1994 TFM distinguished between antiseptic hand

washes and rubs, and between consumer and healthcare personnel antiseptics, but did not change the alcohol concentration originally proposed in 1994.

[4] An inactive ingredient used in over-the-counter (OTC) monograph drugs must meet the requirements of 21 CFR 330.1(e), which requires, among other things, that inactive ingredients must be safe in the amount administered.

See https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/soluciones-cosmeticas-sa-de-cv-609057-08042020

47. Decedent purchased and used BHS in essentially the same condition as when it left Defendants' possession and was placed into the stream of commerce by Defendants. Decedent used BHS in a manner reasonably foreseeable and intended by Defendants, and in which Defendants knew or should have known that BHS would be used.

48. BHS was not properly designed or manufactured by Defendants and was otherwise mislabeled and was not accompanied by proper warnings. BHS was not properly tested, inspected, packaged, or shipped. Most significantly, BHS was inherently unsafe in that it contained undisclosed amounts of a potent and deadly poison, methanol.

49. Defendants failed to perform proper pre-market testing of BHS, failed to perform proper post-market testing of BHS, and failed to perform proper post-market surveillance of BHS.

50. Defendants put BHS in the stream of commerce, promoted and maintained BHS in the market with full knowledge of its unreasonable risk to the public in general, and specifically to Decedent.

51. In this manner, Defendants violated numerous statutes, standards, and codes of common decency by purposefully placing a deadly poison in BHS and selling it to Decedent. Defendants did this merely to take advantage of the pandemic and make an unlawful profit.

52. Defendants are liable in negligence and are strictly liable as a matter of law under the provisions of the *Restatement (Second) of Torts* § 402A. Defendants are further liable for

statutory violations, negligence, intentional and negligent misrepresentation, and breach of express and implied warranties. At all times material herein, Defendants failed to use the degree of care skill, foresight and caution required under the circumstances and/or by federal law and the law of the Commonwealth of Pennsylvania.

53. Defendants' conduct was willful, intentional, and malicious and done with reckless indifference to the health and safety of Decedent and the general public. As a result of said reckless and willful conduct, Decedent suffered severe and terminal injuries, prolonged conscious pain, suffering and economic loss, and Plaintiffs therefore claim the full measure of punitive damages available under Pennsylvania law.

54. Here, Defendants knowingly took advantage of a global pandemic with reckless disregard to the most vulnerable. Simply stated, Defendants poisoned Decedent to death.

COUNT I
STRICT LIABILITY IN TORT BASED UPON VIOLATION OF STATUTE

55. The foregoing allegations are all hereby incorporated in their entirety.

56. Defendants violated the applicable laws, standards and regulations as set forth above, and otherwise deprived the FDA of information necessary to make informed judgments concerning the safety of BHS.

57. By knowingly, and without proper warnings or descriptions, placing a product that was hazardous, poisonous, unavoidably dangerous, and defective in violation of marketing conditions imposed by law in the stream of commerce, Defendants are strictly liable in tort for Decedent's injuries.

58. BHS reached Decedent in a defective, dangerous, and ultimately deadly condition, and thereafter brought about Decedent's untimely death.

59. In this manner, Defendants have developed, manufactured, marketed, tested, inspected, shipped, supplied, distributed and sold BHS with gross, willful, malicious, reckless and outrageous disregard for the consequences of their actions, inactions and omissions, including a palpable disregard for the consequences of their actions, inactions and omissions on the public in general, and specifically on Decedent.

60. As a direct and proximate result of Defendants' actions, inactions and omissions, Decedent was caused to suffer prolonged, grave, and terminal injuries.

COUNT II
STRICT LIABILITY IN TORT BASED UPON FAILURE TO WARN

61. The foregoing allegations are all hereby incorporated in their entirety.

62. Defendants developed, manufactured, marketed, tested, inspected, shipped, supplied, distributed and sold BHS expecting that it would reach consumers in the condition in which it was manufactured and sold, and knowing, or with reason to know, that it would be used without inspection for defects of the type that killed Decedent.

63. BHS reached Decedent without substantial change in the condition in which Defendants developed, manufactured, marketed, tested, inspected, shipped, supplied, distributed, and sold it.

64. Decedent's particular use of BHS was known and fully anticipated by Defendants.

65. Defendants failed to provide adequate warnings regarding BHS, causing it to be unreasonably dangerous to the intended user.

66. Defendants failed to provide additional or alternative warnings to the warnings it did give regarding BHS, causing it to be unreasonably dangerous to the intended user.

67. Defendants knew or should have known that the given warnings regarding BHS were inadequate.

68. In this manner, Defendants have developed, manufactured, marketed, tested, inspected, shipped, supplied, distributed and sold BHS with gross, willful, malicious, reckless and outrageous disregard for the consequences of their actions, inactions and omissions, including a culpable disregard for the consequences of their actions, inactions and omissions on the public in general, and specifically on Decedent.

69. As a direct and proximate result of Defendants' actions, inactions and omissions, Decedent was caused to suffer prolonged, grave, and terminal injuries.

COUNT III
STRICT LIABILITY IN TORT BASED UPON DESIGN DEFECT

70. The foregoing allegations are all hereby incorporated in their entirety.

71. BHS was defectively designed and formulated, causing it to be unreasonably dangerous at the time it left Defendants' possession.

72. At least one alternative design for BHS was available to Defendants at all relevant times. The alternative design was practical, feasible, and would have reduced or eliminated the foreseeable risk of harm to Decedent.

73. BHS was defective and unreasonably dangerous to consumers and the market was rife with examples of safer, non-poisonous hand sanitizers that were much more effective for eliminating microbes and germs.

74. The foreseeable risks of a poisonous hand sanitizer obviously exceeded any possible benefit of the product, which was dangerous beyond any reasonable consumer's expectations or ability to determine the true and deadly nature of the product.

75. As a direct and proximate result of the unreasonably dangerous and defective condition of BHS, Decedent was injured and killed.

76. Because of the unreasonably dangerous and defective condition of BHS, Defendants breached common law product liability duties and § 402A of the *Restatement (Second) of Torts*.

77. In this manner, Defendants have developed, manufactured, marketed, tested, inspected, shipped, supplied, distributed and sold BHS with gross, willful, malicious, reckless and outrageous disregard for the consequences of their actions, inactions and omissions, including a culpable disregard for the consequences of their actions, inactions and omissions on the public in general, and specifically on Decedent.

78. As a direct and proximate result of Defendants' actions, inactions and omissions, Decedent was caused to suffer prolonged, grave, and terminal injuries.

COUNT IV
STRICT LIABILITY IN TORT BASED UPON MANUFACTURING DEFECT

79. The foregoing allegations are all hereby incorporated in their entirety.

80. BHS was laced with methanol during the manufacturing process and therefore varied from intended design, which rendered it defective and unreasonably dangerous at the time it left Defendants' possession.

81. The lack of proper procedures, standards, workmanship, raw materials, labeling, quality control, best practices and/or industrial hygiene in Defendants' manufacturing process caused BHS to contain a potent and deadly poison.

82. As a direct and proximate result of the unreasonably dangerous and defective condition of BHS, Decedent was injured and killed.

83. Because of the unreasonably dangerous and defective condition of BHS, Defendants breached common law product liability duties and § 402A of the *Restatement (Second) of Torts.*

84. In this manner, Defendants have developed, manufactured, marketed, tested, inspected, shipped, supplied, distributed and sold BHS with gross, willful, malicious, reckless and outrageous disregard for the consequences of their actions, inactions and omissions, including a culpable disregard for the consequences of their actions, inactions and omissions on the public in general, and specifically on Decedent.

85. As a direct and proximate result of Defendants' actions, inactions and omissions, Decedent was caused to suffer prolonged, grave, and terminal injuries.

COUNT V
NEGLIGENCE

86. The foregoing allegations are all hereby incorporated in their entirety.

87. Defendants owed a duty to Decedent and the public in general to safely and reasonably research, develop, test, manufacture, produce, market, promote, distribute, and sell BHS. In particular, Defendants owed a duty to Decedent and the public in general not to put poison in their consumer products, fail to disclose that fact and then continue to deny that they had done so.

88. Decedent justifiably relied upon Defendants to properly discharge those duties, and Defendants breached those duties.

89. In this manner, Defendants have developed, manufactured, marketed, tested, inspected, shipped, supplied, distributed and sold BHS with gross, willful, malicious, reckless and outrageous disregard for the consequences of their actions, inactions and omissions, including a culpable disregard for the consequences of their actions, inactions and omissions on the public in general, and specifically on Decedent.

90. As a direct and proximate result of Defendants' reckless, wanton, and negligent conduct, Decedent was caused to suffer prolonged, grave, and terminal injuries.

COUNT VI
NEGLIGENT MISREPRESENTATION

91. The foregoing allegations are all hereby incorporated in their entirety.

92. Defendants owed a duty to Decedent and the public in general to safely and reasonably research, develop, test, manufacture, produce, market, promote, distribute, and sell BHS. In particular, Defendants owed a duty to Decedent and the public in general not to put poison in their consumer products, fail to disclose that fact and then continue to deny that they had done so.

93. Defendants made misrepresentations of material facts with the intent to induce others to act upon those misrepresentations.

94. These misrepresentations were made under circumstances in which Defendants ought to have known of the falsity of the misrepresentations, including selling poison to an unknowing public during a pandemic.

95. Defendants had a duty to tell the truth, and a duty to make a reasonable investigation of the truth the misrepresentations, especially under these circumstances.

96. Decedent justifiably relied upon Defendants to properly discharge those duties, and Defendants breached those duties.

97. As a direct and proximate result of Defendants' reckless, wanton, and negligent conduct, Decedent was caused to suffer prolonged, grave, and terminal injuries.

COUNT VII
BREACH OF EXPRESS WARRANTY

98. The foregoing allegations are all hereby incorporated in their entirety.

99. Defendants expressly warranted to Decedent and the public in general that BHS was merchantable, fit, safe and effective for its reasonably anticipated uses.

100. The BHS purchased and used by Decedent was unsafe, unmerchantable, and unfit for human use, in that it contained a potent and deadly poison.

101. Defendants were aware that Decedent was relying upon Defendants' skill and judgment to research, develop, test, manufacture, produce, market, promote, distribute, and sell a product that was safe and effective for its reasonably anticipated uses.

102. Defendants breached the express warranties of merchantability to Decedent and the public in general because BHS was unmerchantable, unfit, unsafe, and ineffective for its reasonably anticipated use.

103. As a direct and proximate result of Defendants' breach of the express warranties of merchantability and fitness, Decedent was caused to suffer prolonged, grave, and terminal injuries.

COUNT VIII
BREACH OF IMPLIED WARRANTY

104. The foregoing allegations are all hereby incorporated in their entirety.

105. Defendants impliedly warranted to Decedent and the public in general that BHS was merchantable, fit, safe and effective for its reasonably anticipated uses.

106. The BHS purchased and used by Decedent was unsafe, unmerchantable, and unfit for human use, in that it contained a potent and deadly poison.

107. Defendants were aware that Decedent was relying upon Defendants' skill and judgment to research, develop, test, manufacture, produce, market, promote, distribute, and sell a product that was safe and effective for its reasonably anticipated uses.

108. Defendants breached the implied warranties of merchantability to Decedent and the public in general because BHS was unmerchantable, unfit, unsafe, and ineffective for its reasonably anticipated use.

109. As a direct and proximate result of Defendants' breach of the implied warranties of merchantability and fitness, Decedent was caused to suffer prolonged, grave, and terminal injuries.

COUNT IX
PUNITIVE DAMAGES

110. The foregoing allegations are all hereby incorporated in their entirety.

111. Defendants' conduct was malicious, wanton, reckless, willful, and oppressive, and done with reckless indifference to the health and safety of Decedent and the general public.

112. Defendants' acts were outrageous, carried out with a flagrant disregard for the rights of others, including Decedent, and with actual awareness that such acts and failures to act would, in reasonable probability, result in severe injury and death.

113. As a result of Defendants' reckless and willful conduct, Decedent was caused to suffer prolonged, grave, and terminal injuries.

114. Plaintiffs are therefore entitled to the full measure of punitive damages available under Pennsylvania law, sufficient to deter such wrongful, outrageous, and deadly conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment and an award of damages against Defendants, jointly and severally, as follows:

a. special damages, to include medical and incidental expenses;

b. past and future loss of earnings and/or earning capacity;

c. general damages, to include pain and suffering, emotional distress, and mental anguish;

d. delay damages, pre-judgment and post-judgment interest;

e. punitive damages;

f. costs and attorneys' fees; and

g. any other legal and equitable relief that the Court deems necessary, just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury of all claims so triable.

Dated: 12/07/2021

Respectfully submitted,

STARK & STARK, P.C.

Martin P. Schrama (PA 324828)
Stefanie Colella-Walsh (PA 205709)
993 Lenox Drive, Building Two
Lawrenceville, New Jersey 08648
Phone: (609) 896-9060; Fax: (609) 896-0629
Email: mps@stark-stark.com
scw@stark-stark.com

Attorneys for Plaintiffs